

REMARKS

Priority

The Examiner objected to the disclosure of the prior-filed application, non-provisional U.S. Application Interim Serial No. P-107,891, for failing to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 because the application is not identifiable/available based on the interim serial number provided.

Applicant has amended the specification to include the US serial number.

Information Disclosure Statement

Applicant acknowledges that the IDS is being considered by the Examiner and the typographical correction made by the Examiner.

Oath and Declaration

The Examiner objected to the oath or declaration is required because it is not apparent that the pending application is a Continuation-In-Part of non-provisional U.S. Application Interim Serial No. P 107,891.

Applicant acknowledges that a new Oath or Declaration correctly identifying the application by its US serial number is required and will provide a new Declaration in due time.

Specification

In point 6 the Examiner objected to the specification because in the cross-reference to related application section of the specification it states the application is a

continuation-in-part of non-provisional U.S. Application Interim Serial No. P-107,891, but no such application appears of record.

Applicant has amended the specification to include the US serial number.

In point 7 the abstract of the disclosure is objected to because: The second sentence begins with the word, "These", which describes a plurality of methods.

Applicants have amended the Abstract as suggested by the Examiner.

In point 8 the specification is objected to because on page 6, line 10, the quotation mark is misplaced.

Applicant has amended the specification accordingly.

Claim Objections

In point 10, Claim 16 is objected to because the abbreviation 'HIC' should be identified at the first occurrence.

Applicant has amended Claim 16 accordingly.

In point 11, Claims 17 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant has addressed the objection by specifying that the protein is "growth hormone antagonist" rendering the rejection moot.

In point 12, Claim 26 is objected to because the abbreviation, UF/DF#3 should be identified at the first occurrence.

Applicant has amended Claim 26 accordingly.

Claim Rejections – 35 USC § 112

In point 15, Claim 2 is rejected because it recites the limitation "said protein" in the 2nd line. There is insufficient antecedent basis for this limitation in the claim.

As suggested by the Examiner, applicant has amended Claim 2 to recite "...a partially pegylated form of the protein..."

In point 16, Claims 12, 15, and 20 are rejected as depending from cancelled claims.

Applicant has amended Claim 12 to depend from Claim 8, Claim 15 to depend from Claim 2, and Claim 20 to depend from Claim 17.

In point 17, Claim 16 is rejected because it recites a hydrophobic interaction chromatography step (a2) and depends from independent claim 1. There is no step (a1) in claim 1.

Applicant has amended Claim 16 to delete the step enumeration "(a2)".

In point 18, Claim 26 is rejected because it recites a step (a3), but no step (a1) is recited in the method steps.

Applicant has amended Claim 26 to depend from Claim 17.

In point 19, Claim 43 is rejected because it recites the limitation "said pegylated protein" and "said protein" in the 1st line and 4th line of the claim. There is insufficient antecedent basis for these limitations in the claim.

As suggested by the Examiner applicant has amended Claim 51 to recite "The process of claim 1 wherein said pegylated protein isoforms comprises one or more of said pegylated protein the isoforms PEG-1, PEG-2. . .and any unpegylated impurity of the said protein and any free PEG molecules."

In point 20, Claim 51 is rejected because it recites the limitation "said pegylated protein" in the 1st line of the claim. There is insufficient antecedent basis for this limitation in the claim.

As suggested by the Examiner applicant has amended Claim 51 to recite "The process of claim 1 wherein said pegylated protein isoforms comprises one or more of said pegylated protein the isoforms PEG-1, PEG-2...."

In point 21, Claim 54 is rejected because it is unclear how ion exchange chromatography does not encompass anion exchange and cation exchange chromatography.

As suggested by the Examiner applicant has amended Claim 54 to delete the phrase "ion exchange (IEX) chromatography".

In view of the amendments to the claims applicant submits that the rejections under 35 USC § 112 are moot and it is requested that the rejections be withdrawn.

Claim Rejections - 35 USC § 102

In point 22 the Examiner rejected Claims 1, 2, 8, 15, 31, and 37 under 35 U.S.C. 102(b) as being anticipated by Bona et al. (U.S. Patent 5,969,109).

Applicant has addressed the rejection of Claims 1, 2, 8, 15, 31, and 37 by specifying that the protein is "a growth hormone antagonist" rendering the rejection

moot. Claim 1 has been amended to recite “ . . . pegylated protein isoforms, wherein the pegylated protein is a growth hormone antagonist . . .” Support for the amendment can be found in the Field of the Invention section ([0002] – *for clarity and the Examiner’s convenience applicant has cited the paragraph numbers as published by the USPTO - US2005/0085631 A1), [0075]* where “pegylated protein” is defined to include a “growth hormone antagonist”, and as is exemplified in the Examples.

In point 24, Claims 1, 2, 8, 15, 31, 37, and 54 are rejected under 35 U.S.C. 102(e) as being anticipated by Papadimitriou (U.S. 2002/0037841 A1).

Applicant has addressed the rejection of Claims 1, 2, 8, 15, 31, 37, and 54 by specifying that the protein is “a growth hormone antagonist” rendering the rejection moot.

In point 25, Claims 1-5, 8, 12, 15, 31, 37, 40, and 54 are rejected under 35 U.S.C. 102(e) as being anticipated by Finn et al. (U.S. 2003/0171285 A1; Effective filing date = November 20, 2001).

Applicant has addressed the rejection of Claims 1-5, 8, 12, 15, 31, 37, 40, and 54 by specifying that the protein is “a growth hormone antagonist” rendering the rejection moot.

In view of the amendments to the claims applicant submits that the rejections under 35 USC § 102 are moot and it is requested that the rejections be withdrawn.

New Claims 205-215 have been added. Support for Claims 205-209 can be found in [0075] where “pegylated protein” is defined to include a “human growth hormone antagonist”, including “B-2036”. Additional support for B-2036 is found in [0003] and as exemplified in the Examples. Support for Claim 210 can be found in the Sequence Listing as filed and in [0004] where the identity of the SEQ ID NO:1 is defined. Support

for claims 211-217 can be found respectively in claims 77, 84, 85, 144, 146, 95, and 98 as originally filed. No new matter has been added.

Conclusion

Claims 1-5, 8, 12, 15-17, 20, 23, 26, 31, 34, 37, 40, 43, 51, 54 & 205-217 are pending. New Claims 205-217 have been added herewith. Claims 6-7, 9-11, 13-14, 18-19, 21-22, 24-25, 27-30, 32-33, 35-36, 38-39, 41-42, 44-50, 52-53, and 55-204 have been previously canceled. No new matter has been added.

In view of the foregoing amendments and arguments, it is respectfully submitted that all claims now pending in the present application are in condition for allowance. Therefore, swift passage of the application and claims to issue is respectfully requested.

Respectfully submitted,



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